

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004M–0147, 2004M–0145, 2004M–0207, 2004M–0253, 2004M–0165, 2004M–0200, 2004M–0199, 2004M–0256, 2004M–0248, 2004M–0249, 2004M–0250, 2004M–0260, and 2004M–0259]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Think Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2004, through June 30, 2004. There were no denial actions during this

period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2004 THROUGH JUNE 30, 2004.

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P890064(S9)/2004M-0147	Digene Diagnostics, Inc.	DIGENE HYBRID CAPTURE 2 (HC2) HIGH-RISK HPV DNA TEST	March 31, 2003
P020006/2004M-0145	Enteric Medical Technologies, Inc.	ENTERYX PROCEDURE KIT	April 22, 2003
P970027/2004M-0207	Abbott Laboratories	ABBOTT AXSYM ANTIBODY TO HCV	February 5, 2004
P980007/2004M-0253	Abbott Laboratories	AXSYM FREE PSA	February 5, 2004
H020008/2004M-0165	Stryker Biotech	OP-1 PUTTY	April 7, 2004
P010014/2004M-0200	Biomet, Inc.	OXFORD MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	April 21, 2004
P030032/2004M-0199	Genzyme Biosurgery	HYLAFORM (HYLAN B GEL)	April 22, 2004
P030017/2004M-0256	Advanced Bionics Corp.	Precision Spinal Cord Stimulation (SCS) System	April 27, 2004
P030023/2004M-0248	Ophtec USA, Inc.	OCULOID/STABLEYES CAPULAR TEN- SION RINGS	April 27, 2004
P000054/2004M-0249	Wyeth Pharmaceuticals, Inc.	INFUSE BONE GRAFT	April 30, 2004
P030035/2004M-0250	St. Jude Medical	ST. JUDE FRONTIER BIVENTRICULAR CARDIAC PACING SYSTEM	May 13, 2004
P010062/2004M-0260	Euclid Systems Corp.	EUCLID SYSTEMS ORTHOKERATOLOGY (OPRIFOCOM A) CONTACT LENS FOR OVERNIGHT WEAR	June 7, 2004
P030045/2004M-0259	Ev3 Inc.	INTRASTENT DOUBLESTRUT STENT	June 8, 2004

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: September 23, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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